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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/884,434	06/19/2001	Rudy A. Mazzocchi	723.020US1	9942

21186 7590 05/06/2003

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EXAMINER

RUDDY, DAVID M

ART UNIT PAPER NUMBER

3739

DATE MAILED: 05/06/2003

(1)

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/884,434

Applicant(s)

MAZZOCCHI ET AL.

Examiner

David M Ruddy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period of Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-14, 16, 17, 24, 25 and 32-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-14, 16, 17, 24, 25 and 32-39 is/are rejected.
- 7) ☐ Claim(s) 40-43, 45 and 46 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 7-14, 37, 38, 39, and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Schmidt (patent #5,634,932). Schmidt discloses a system comprising an elongate probe (item 200) including proximal and distal ends and having dimensions meeting the size limitations set forth in claim 1 (column 6, lines 60-65) and an aneurysm treatment device (see figures 11-12) carried by the probe. In regard to the limitations of claims 7-8, Schmidt discloses titanium materials, which are compatible with MR imaging, in column 2, lines 20-43 and column 5, line 59.

As seen in figures 11-12 the aneurysm treatment device includes a clip structure having substantially open and closed positions sized to allow treatment of an aneurysm.

The limitations of claim 12 are met by either of the elements 140 or 160.

The examiner acknowledges Applicant's new limitations further reciting that the probe includes "a substantially uniform cylindrical outer surface that is sized and shaped to be accepted within and guided by a similarly sized and shaped lumen of a trajectory guide device." It is the examiner's position that the probe device (item 200) as seen in figure 12 discloses just that. Regardless of the "irregularity of surface" with respect to the other elements disclosed by Schmidt, the outer surface of the probe member (200)

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is disclosed in no other way that substantially uniform and cylindrical. It is also the examiner's position that in so far as the device is to be applied to the interior of a patient's body and in particular a patient's brain (see the first line of the Background of the invention) the device will inherently include the use of a stereotaxic catheter/electrode trajectory guide system (see the discussion of inherency in MPEP 2112). The examiner further states that the use of such stereotaxic catheter/electrode trajectory guide systems are so inherent in the art that they have acquired their own subclass in the USPTO patent classification system (class 606 subclass 130).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidt. With reference to the above rejections Schmidt further discloses an elongate member (item 160), a strand (item 162 or 164), and a ring (item 100). While Schmidt discloses an elongate member (item 160), that item is not disclosed as a "tube".

Applicant has set forth no criticality as to why a "tube" shape of the elongate member is necessary, for any particular purpose, or solves any stated problem and it appears that the invention would work equally well in the embodiment disclosed by

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Schmidt. Accordingly the use of a tube shape for the elongate member appears to be an obvious matter of engineering design.

Claims 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidt in view of Sheldon et al (patent #4,386,602). With reference to the above rejections, Schmidt discloses all that is claimed except the use of a stereotaxic type entry device which uses a first securing mechanism to secure the entry device in association with a subject's skull and a second securing mechanism to secure an orientation of a trajectory guide portion to define a surgical path.

The examiner takes official notice of the use of surgical tool positioning mechanisms used to (1) secure an entry device in association with a subjects treatment area (in this case the skull) and (2) to secure an orientation of a trajectory guide in order to define a surgical path.

Sheldon et al. disclose one such device which includes (as seen in figure 1) a first securing mechanism (item 10) to secure the entry device in association with a subject's skull and a second securing means (see the elements which allow for the vertical adjustment of the position of item 12 in figure 1) for setting a trajectory orientation. The use of such positioning means are old and well known in the art of surgical device (so much so that the systems have acquired their own subclass in the US patent Classification system, class 606 / subclass 130) and would have been obvious to one having ordinary skill in the art at the time the invention was made in order to precisely position the surgical device to assure proper patient treatment.

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Accordingly, it would have been obvious to one having ordinary skill in the art, for the reasons explained above, to use the system of Sheldon et al. for the device of Schmidt.

Claims 2-5 and 32-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidt in view of Gillies et al (patent #6,272,370). With reference to the rejections above Schmidt disclose all that is claimed except an expressed disclosure of an MR imaging device.

Gilles et al. disclose an MR imaging device using a microcoil arrangement (see figure 3 item 16) which can be utilized in surgical treatment for positioning instruments within a patient's skull (see figure 1). Such a system is advantageous in that it provides a clearer image and more specific positioning data than other prior art systems such as a fluoroscope. The system of Gilles et al. promotes greater patient safety and more precise instrument placement. Accordingly it would have been obvious to one having ordinary skill in the art, for the reasons explained above, to use the device of Gilles et al. for the device of Schmidt.

Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidt in view of Gillies et al. (patent #6,272,370) and further in view of Sheldon et al. With reference to the above rejections, Schmidt in view of Gilles et al. disclose all that is claimed except the use of a stereotaxic type entry device which uses a first securing mechanism to secure the entry device in association with a subject's skull and a second

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securing mechanism to secure an orientation of a trajectory guide portion to define a surgical path.

The examiner takes official notice of the use of surgical tool positioning mechanisms used to (1) secure an entry device in association with a subjects treatment area (in this case the skull) and (2) to secure an orientation of a trajectory guide in order to define a surgical path.

Sheldon et al. disclose one such device which includes (as seen in figure 1) a first securing mechanism (item 10) to secure the entry device in association with a subject's skull and a second securing means (see the elements which allow for the vertical adjustment of the position of item 12 in figure 1) for setting a trajectory orientation. The use of such positioning means are old and well known in the art of surgical device (so much so that the systems have acquired their own subclass in the US patent Classification system, class 606 / subclass 130) and would have been obvious to one having ordinary skill in the art at the time the invention was made in order to precisely position the surgical device to assure proper patient treatment. Accordingly, it would have been obvious to one having ordinary skill in the art, for the reasons explained above, to use the system of Sheldon et al. for the device of Schmidt in view of Gilles et al.

Response to Arguments

Applicant's arguments filed 2/13/2003 have been fully considered but they are not persuasive. With respect to Applicant's arguments on page 7 of the most recent

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response that the reference of Schmidt does not disclose a substantially uniform cylindrical outer surface, the examiner respectfully disagrees. With reference to item 200 of drawing figure 12, it is the examiner's position that such an outer surface is in fact disclosed and further that the use of a stereotaxic catheter/electrode trajectory guide system is inherent in this particular field of art.

With respect to Applicant's arguments on page 7 of the most recent response that the reference of Schmidt is expressly directed toward surgical procedures requiring visual observations, the examiner respectfully disagrees. With reference to Column 2, lines 20-43 the exact opposite is contention is expressed, with respect to the use of the plethora of imaging means disclosed (and in particular their usefulness with a titanium material as used here). Why else would such imaging means be so disclosed if the only intention of the device of Schmidt was for visual observation?

With respect to Applicant's arguments on page 7-9 of the most recent response that the reference of Schmidt does not disclose an imagable fiducial structure, the examiner respectfully disagrees. With respect to the titanium materials disclosed in column 5, line 59, the device of Schmidt does in fact disclose such a structure.

With respect to Applicant's arguments in the most recent response that the reference of Schmidt does not disclose a treatment device extendable and retractable into a probe, the examiner respectfully disagrees. The probe item 200 of figure 12 and the interaction with this element by item 100 disclose just such a system.

Conclusion

Claims 40-43 and 45-46 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not teach an aneurysm treatment probe including the corresponding inner and outer lumen structures as recited in combination with the limitations of the preceding claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

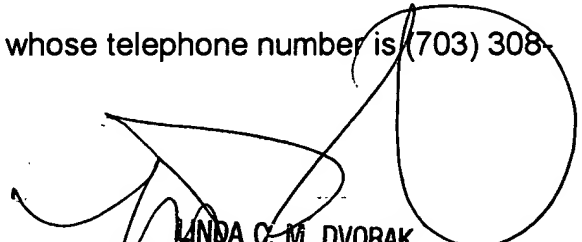
Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M Ruddy whose telephone number is (703) 308-3595. The examiner can normally be reached on Mon-Fri 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (703) 308-0994. The fax phone numbers

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for the organization where this application or proceeding is assigned are (703) 746-3376 for regular communications and (703) 746-3376 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.



LINDA C. M. DVORAK
SUPERVISORY PATENT EXAMINER
GROUP 3700

DR
May 1, 2003